

PATENT COOPERATION TREATY

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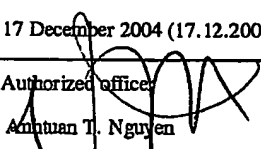
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 1135-SPCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US03/28878 | International filing date (day/month/year) 12 September 2003 (12.09.2003) | Priority date (day/month/year) 13 September 2002 (13.09.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/00 and US Cl.: 606/61 | | |
| Applicant REPLICATION MEDICAL, INC. | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | |
| Date of submission of the demand 08 April 2004 (08.04.2004) | Date of completion of this report 17 December 2004 (17.12.2004) | |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer  Anh Tuan T. Nguyen Telephone No. (703) 308-0858 | |

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/28878

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
 pages 1-27 as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 28-33 as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-18 as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/28878**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

| | | |
|-------------------------------|--|-----|
| Novelty (N) | Claims 1010-12,14,15,17-20,24-28,33-35,42,43 | YES |
| | Claims 1-9,13,16,21-23,29-32,36-41 | NO |
| Inventive Step (IS) | Claims 10-12,14,15,17-20,24-28,33-35,42,43 | YES |
| | Claims 1-9,13,16,21-23,29-32,36-41 | NO |
| Industrial Applicability (IA) | Claims 1-43 | YES |
| | Claims NONE | NO |

2. CITATIONS AND EXPLANATIONS

Claims 37-40 lack novelty under PCT Article 33(2) as being anticipated by Drake (US 3,705,581). In Fig. 2, Drake discloses a surgical instrument capable of "driving a folded intervertebral implant through a tube and into body comprising: a body portion, a fixed handle 12, a movable handle 16, a pusher ride 26, ratchet teeth 36, a latch 18, a bias spring, and a secondary ratchet 38.

Claim 1-9, 13 and 16 lack novelty under PCT Article 33(2) as being anticipated by Moskovich (US 5,431,658). In Fig. 6, Moskovich discloses a tool fully capable of manipulating a flexible intervertebral implant comprising: a guide assembly 1 and 2 having a chamber therein, a manipulation assembly 21, 23 and 26, an opening, a manipulation member 26, a connector 25, a drive pin 24, a holder (located at the distal end of the guide assembly), a plunger 25 and 26, and an implant 5.

Claims 21-23 lack novelty under PCT Article 33(2) as being anticipated by Sherwin (US 3,750,652). In Fig. 1, Sherwin discloses a folding apparatus comprising a folding device 11 and 12 having jaws, the jaws having a defining a variable size recess, a drive member 18 and 20, and a guide member 42. The device is inherently capable of folding an intervertebral implant. For example, a disc-shaped implant as disclosed by applicant may be placed between the jaws, with the outer edges engaging the jaws. The jaws may be closed upon the implant causing the disc to bend and fold.

Claims 10-12, 14, 15, 17-20, 24-28, 33-35, 42 and 43 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest all of the limitations of the claims including a storage member (claim 17), an implantation tube (claim 29), "a transfer sleeve having first and second nuts mounted thereon and a lock member..." (claim 31), a transfer tube, a working sleeve, and a surgical instrument "engageable with the proximal end of the transfer tube" (claim 41), "inserting an intervertebral implant in to the recess" (claim 42).

Claims 1-42 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 29, 30 and 41 lack novelty under PCT Article 33(2) as being anticipated by GRABEK. Grabek discloses a "folding apparatus" comprising jaws, a pusher and a tube.

Claims 31, 32 and 36 lack novelty under PCT Article 33(2) as being anticipated by TOURTELLOTTE. Tourtellotte discloses "transfer sleeve" having first and second nuts and a lock member with a working sleeve (Fig. 1)

NEW CITATIONS

US 5 931 810 a (GRABEK) 03 August 1999, see Fig. 1.

US 5 961 248 A 9TOURTELLOTTE) 05 October 1999, see Fig. 1.